



**U.S. Department of Health and Human Services
Office of Public Health Emergency Preparedness**

Implementing Project BioShield:

Acquisition of Medical Countermeasures for Biodefense

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Biodefense for the US Government

Unprecedented opportunity

- A top priority and dedicated commitment among senior leaders of this Administration
- Generous bipartisan support from Congress
- Solid scientific foundation
 - Due in large part to the research that has been developed over many years at USAMRIID
 - Rapidly increasing database of basic research information about pathogens using 21st century biotechnologies such as genomics
- A strong private sector



Biodefense for the 21st Century

- Essential Pillars of national biodefense
 - ▶ Threat Awareness
 - Anticipation of Future Threats
 - ▶ Prevention and Detection
 - ▶ Surveillance and Detection
 - ▶ Response and Recovery
 - Capabilities required for response will be based on interagency-agreed scenarios that are derived from plausible threat assessments.
 - Mass Casualty Care
 - Risk Communication
 - Decontamination
 - **MEDICAL COUNTERMEASURE DEVELOPMENT**
- HHS will continue to lead the effort to ensure the development and availability of sufficient quantities of safe and effective medical countermeasures to mitigate illness and death in the event of a biological weapons attack.



Project BioShield

Announced by President Bush in his State of the Union address on 28 January 2003.



Purpose: To accelerate the process of research, development, purchase, and availability of effective countermeasures against agents of bioterror.

Secretaries Thompson (HHS) and Ridge (DHS) jointly transmitted the “Project BioShield Act of 2003 to Congress on 26 February 2003.

- The House version of the bill (H.R. 2122) was passed by a vote of 421-2 on 16 July 2003.
- The Senate version of the bill (S. 15) was passed by a vote of 99-0 on 19 May 2004.
- The bill (P.L. 108-276) was signed by the President on 21 July 2004



Project BioShield

Three-pronged program:

- Establishes a secure **funding** source for purchase of critical biomedical countermeasures
- Increases NIH/NIAID **authorities** and flexibility to expedite research and development of critical biomedical countermeasures
- Establishes a FDA **Emergency Use Authorization** for critical biomedical countermeasures



Project BioShield

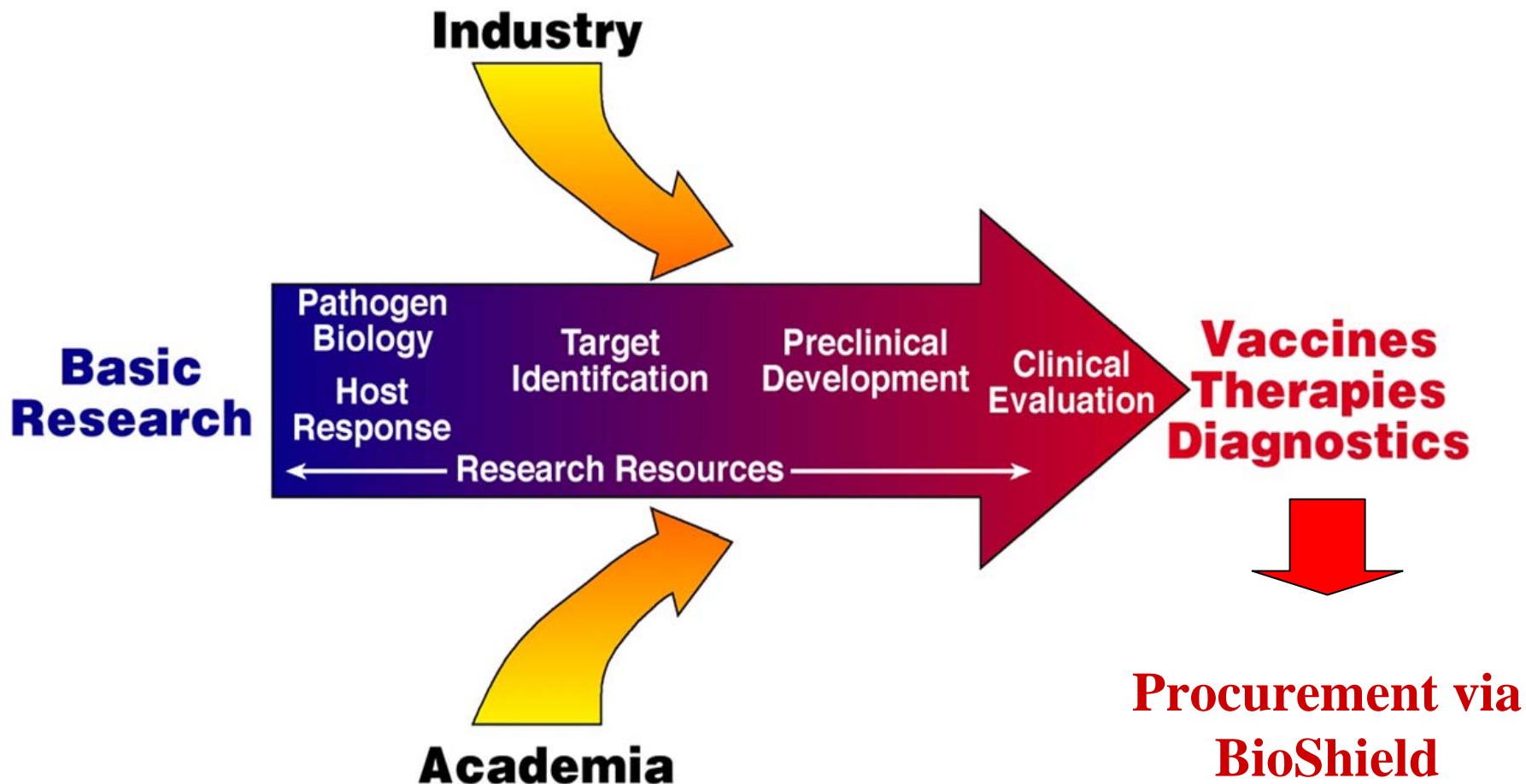
The DHS appropriations bill (PL 108-90) signed by President Bush on 1 October 2003 **created a discretionary reserve of \$5.6 billion to fund the program through FY2013. An amount not to exceed \$3.4 billion may be obligated during FY2004-2008.**

Funding is available for countermeasures once production of licensable products is judged scientifically feasible. **HHS will be the procuring authority.**

Amounts appropriated become available only upon the approval by the President.

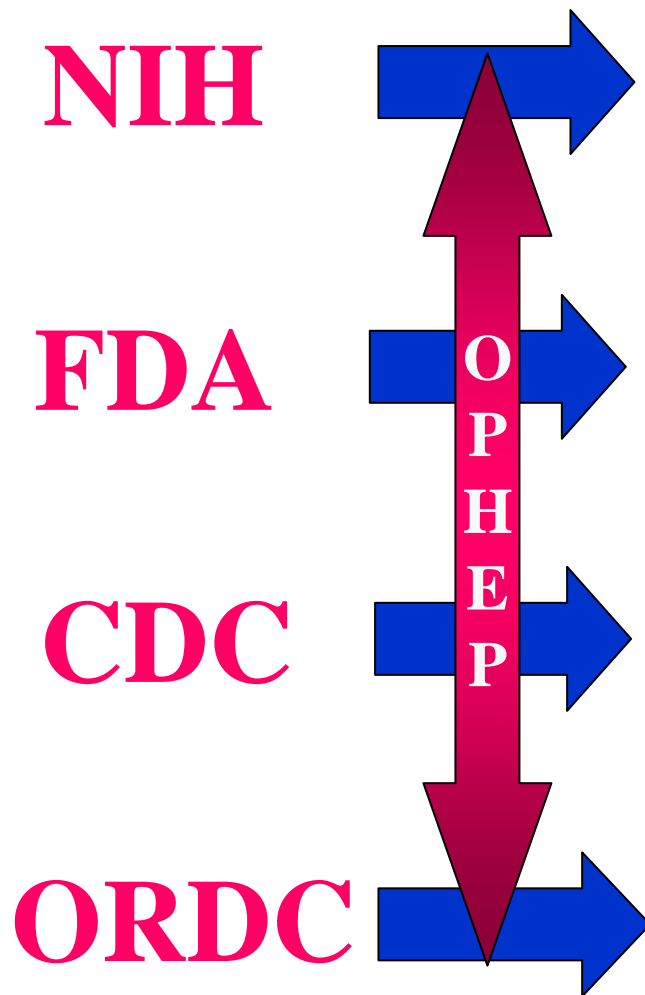


Medical Countermeasures Pipeline





BioShield Implementation: Coordination within HHS



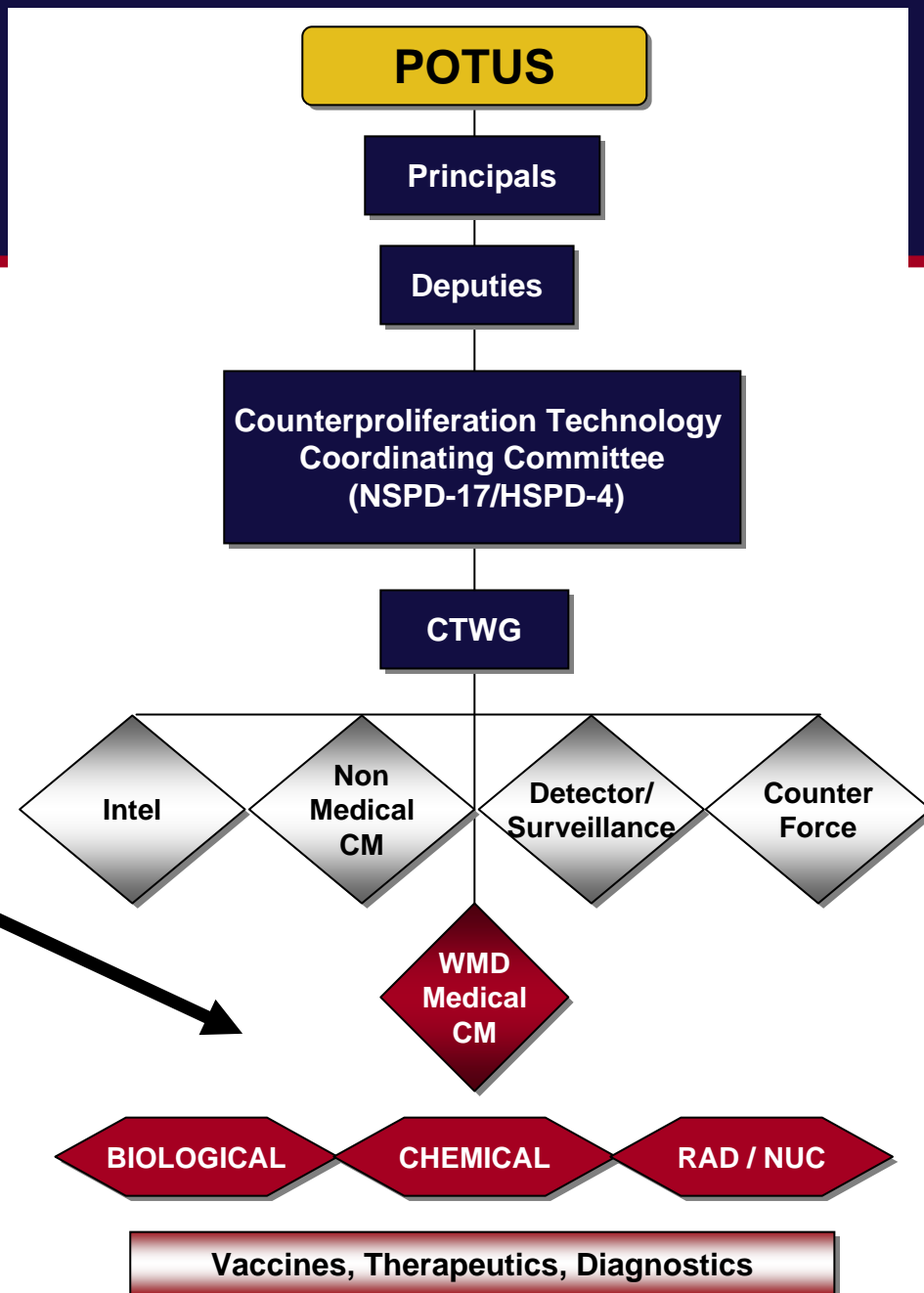
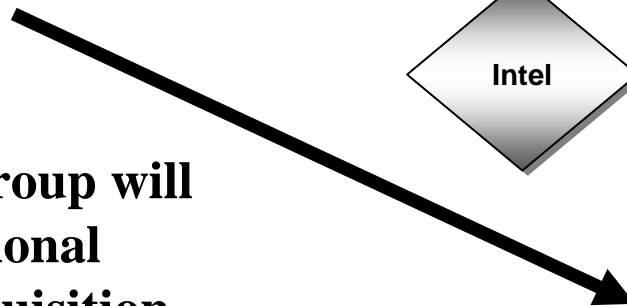
- Build Research Infrastructure
- Conduct Basic Research
- **Develop Medical Countermeasures**
- **Regulatory Approval**
 - Vaccines, Therapeutics, Diagnostics
- **Strategic National Stockpile (SNS)**
- Train Local Response Teams
- Surveillance and Detection
- **Acquire Medical Countermeasures**
 - *Execute Project BioShield*



BioShield: Interagency coordination

**HHS has a leadership role in
the WMD Medical
Countermeasures
Subcommittee**

**This interagency group will
coordinate national
requirements, acquisition
strategies, and requests for
Project BioShield funding**





Bioterrorism Attack Scenarios

- **Department of Homeland Security** has lead responsibility
 - ▶ Directorate of Science and Technology
- A means of understanding and comparing various threats
- Based largely on intelligence
 - ▶ National programs – old and new
 - ▶ Terrorist intentions and capability
- Heavily dependent on scientific and technical knowledge of agents and delivery mechanisms
 - ▶ Significant knowledge gaps become apparent
- Important in judgments on size of stockpile
- Research on the threat agents will improve the quality of the scenarios



Evaluating the Effectiveness of Countermeasures

- Modeling medical consequences and effectiveness of response
 - ▶ HHS responsibility
 - ▶ Uses mathematical models to estimate casualties from an attack scenario and impact on the medical care system
 - ▶ Can be used to evaluate the effectiveness of various medical countermeasures
 - Pre-event vaccination, Post-exposure vaccination, Post-exposure antibiotics, Quarantine and isolation
 - ▶ Value of the models is dependent on the validity of the assumptions
 - Highly sensitive to estimations of infectious dose, transmission rate, incubation period
 - Knowledge gaps become evident and inform research agenda
 - ▶ HHS has begun a program to develop the best models for evaluation of medical countermeasures



Release of BioShield Funds

- Interagency Approval of Requirement
- Findings by Secretaries of DHS and HHS
 - ▶ Determination of material threat
 - ▶ Countermeasures are necessary
 - ▶ Appropriateness of the countermeasure
 - Numbers of doses required
 - Production & delivery is feasible within 8 years
 - Evaluation of commercial market
- Approval by the President



White House photo by Paul Morse



Contract Terms for Project BioShield

- No payment may be made until delivery has been made of a portion of the total number of units contracts for
- Discounted payment for product that is not licensed, cleared, or approved at the time of delivery.
 - ▶ Delivery to the SNS is contingent on the availability of sufficient data to support emergency use
- Vendor must seek approval, clearance, or licensure of product.
 - ▶ Additional payment upon licensure, clearance or approval
- Contract duration will be 5-8 years



RFI: Therapeutics to Treat Neutropenia and Thrombocytopenia Associated with the Acute Radiation Syndrome (ARS)

- RFI issued 10/19/04; responses due 12/20/04
- Solicitation Number **RFI-ORDC-05-01** (<http://www.fedbizopps.gov/>)
- ARS, or radiation sickness, is an acute illness caused by a high dose of penetrating radiation. Exposure results in severe neutropenia and thrombocytopenia.
- The Government has an interest in identifying sources of therapeutics likely to be effective in preventing or reducing the development of neutropenia and/or thrombocytopenia when administered at times after acute exposure to radiation.
 - ▶ The Government is particularly interested in identifying therapeutics that are effective when given several hours to days after exposure.
- Data obtained from this RFI will be used by DHHS in making recommendations and decisions on the development of an appropriate procurement strategy to meet the Nation's bioterrorism defense needs.